Phage-Based Therapies

Dr. Grégory Resch
Department of Fundamental Microbiology
University of Lausanne, Switzerland

ICAAC-ICC 2015, San Diego, Sep. 17th-21st

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et de médecine

Disclosures

Co-inventor: Patent WO 2013052643 A1 licensed to ContraFect Corp. through The Rockefeller University.

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The context

"Then there is the danger that the ignorant man may easily underdose himself and by exposing his microbes to non-lethal quantities of the drug make them resistant."

A. Fleming. Nobel Lecture, Dec. 11, 1945

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The context

The facts

- Patients continue to be victims of antibotic treatment failures
- Infectious diseases due to bacterial resistance could become orphan diseases

Alternative and complementary strategies ?

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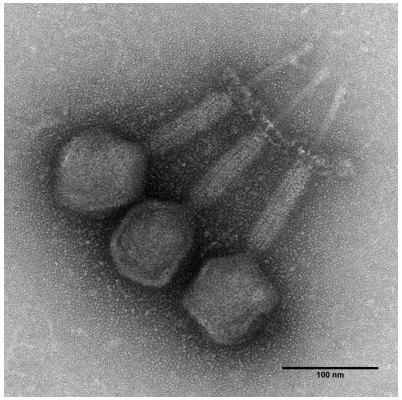
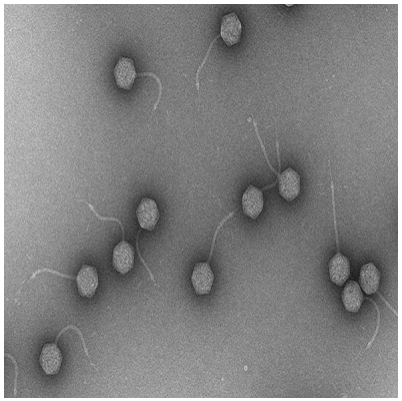
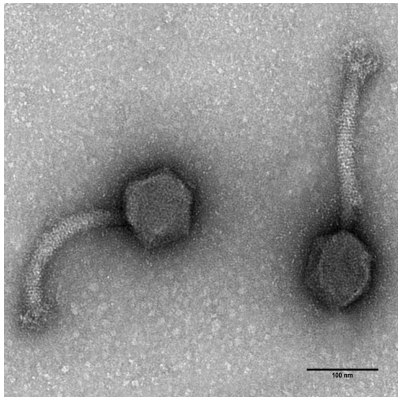
Phage-Based Therapies

Phage Therapy

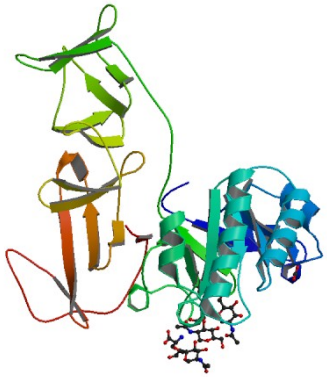




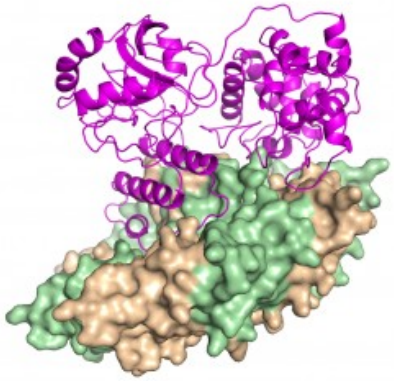


courtesy of Frank Oechslin, DMF, UNIL

Phage Lysins Therapy



Cpl-1; J. Biol. Chem. 282 (34): 24990–9



PlyC; EARTHSKY//SCIENCE WIRE. Jul. 24, 2012

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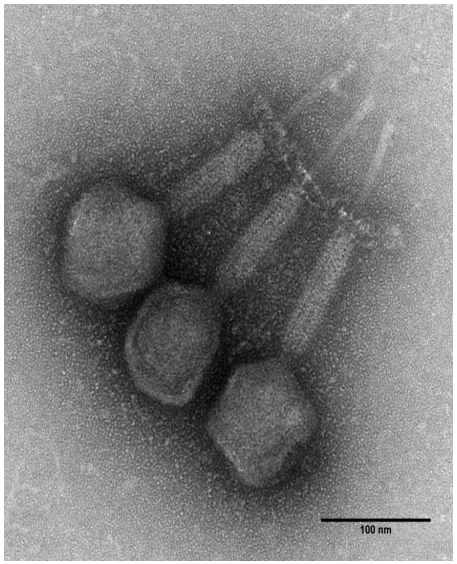
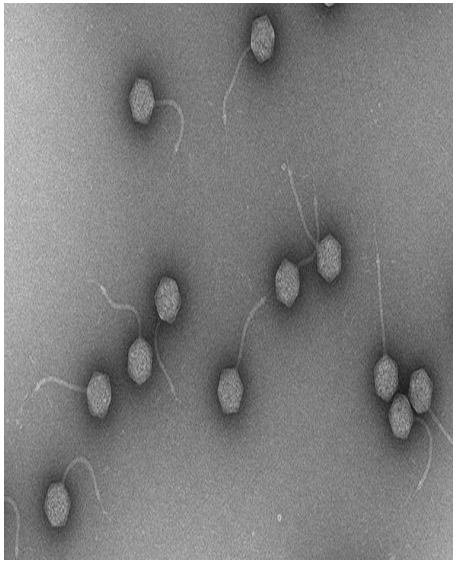
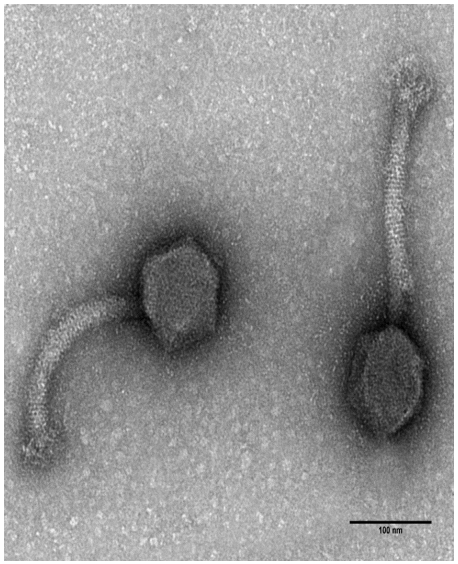
Phage-Based Therapies

Phage Therapy







courtesy of Frank Oechslin, DMF, UNIL

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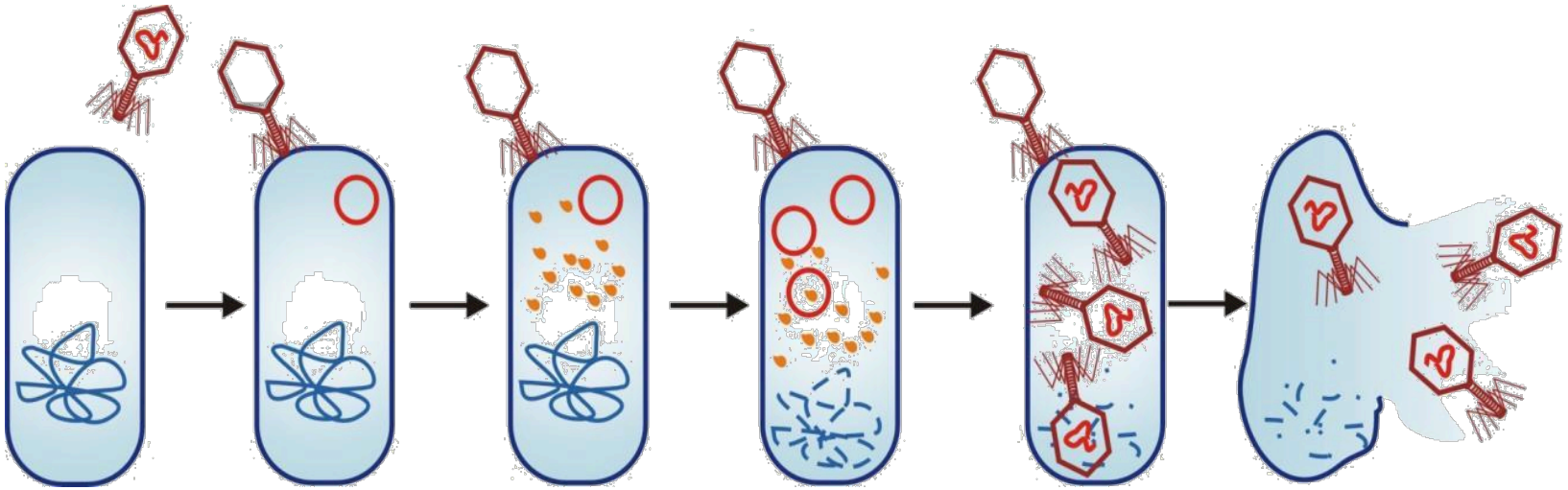
What is behind phage therapy?

The life cycle of lytic bacteriophages



courtesy of De Vos D. (PHAGOBURN kick-off meeting)

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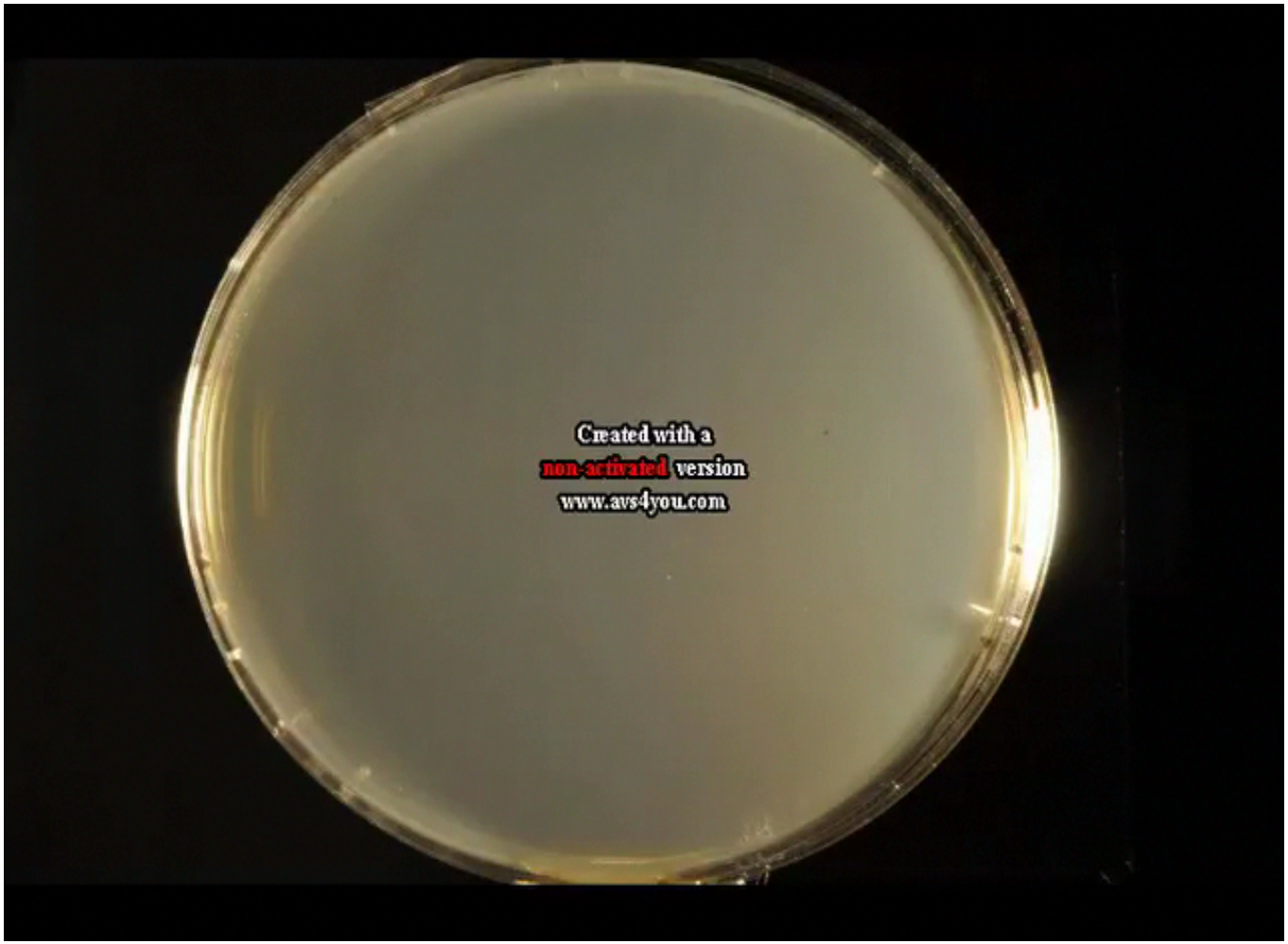
Natural bactericidal power of bacteriophage



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Brief History of Phage Therapy

1919

First success

- 5 children suffering from dysentery (d'Hérelle, Necker hospital, Paris)

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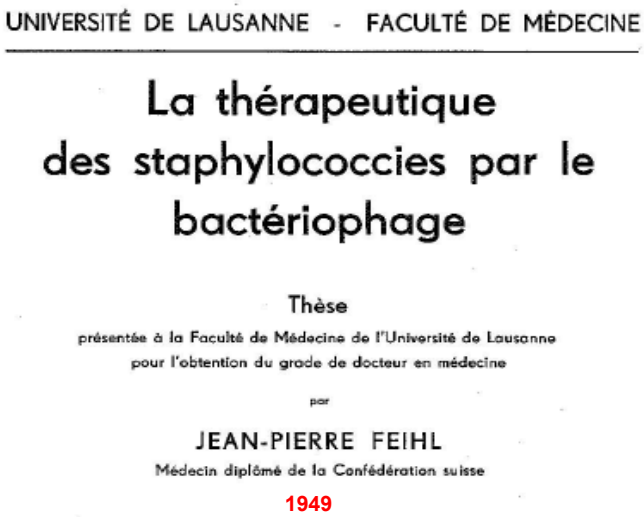
Brief History of Phage Therapy

1920's to 1950's

150 publications/year (successes and failures)

- thyphoïd fever (*S. enterica typhi* and *paratyphi*)
- urinary tract infection (mainly *E. coli*)
- dysentery (diverse *Shigella*)
- bubonic pestis(*Y. pestis*)
- cholera (*V. cholerae*)
- *S. aureus* and *S. pneumoniae* infections



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La thérapeutique des staphylococcies par le bactériophage

Thèse

présentée à la Faculté de Médecine de l'Université de Lausanne pour l'obtention du grade de docteur en médecine

par

JEAN-PIERRE FEIHL

Médecin diplômé de la Confédération suisse

1949

1923: Eliava Institute in Tbilisi, Georgia.

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Brief History of Phage Therapy

Since then

- decline of phage therapy to antibiotherapy.
- last phage preparations available in 1978 on French pharmacy stock lists
- since 30 years, isolated cases of phage therapy treatment in the occidental world (compationate treatment)

Widely used in Georgia, Poland, Russia.

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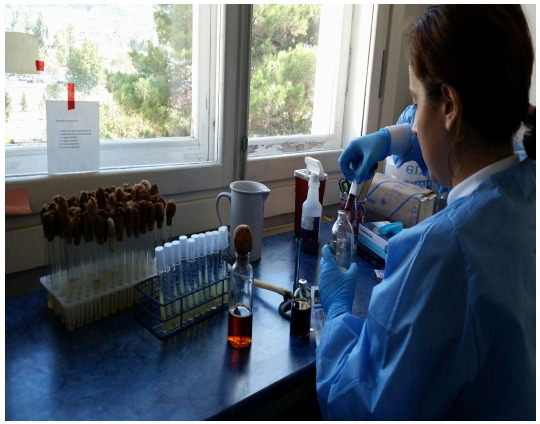
Eliava Phage Therapy Center (2010)



2012-2014

- 3’238 patients (37 hospitalized foreigners + 18 treated abroad)
- Phage preparations sent to 231 patients
- >90% success rate

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Phage Therapy Unit, Wroclaw (2005)

Today in the West

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"
Search for studies: [ ] Search
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Registered Clinical Trials

Phage Therapy Unit, Wroclaw

153 patients from 2008 to 2010 admitted with various infections due to multidrug resistant bacteria

	Genital and urinary tract infections in men[a] (*n* = 29)		Genital and urinary tract infections in women[b] (*n* = 22)		Soft tissue infections[c] (*n* = 30)		Skin infections[d] (*n* = 10)		Orthopedic infections[e] (*n* = 37)		Respiratory tract infections[f] (*n* = 24)	
Category of response to treatment	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
A - pathogen eradication and/or recovery	11	37.9	3	13.6	5	16.7	0	0.0	7	18.9	2	8.3
B - good clinical result	2	6.9	0	0.0	2	6.7	2	20.0	3	8.1	3	12.5
C - clinical improvement	1	3.4	5	22.7	4	13.3	1	10.0	7	18.9	2	8.3
D - questionable clinical improvement	2	6.9	0	0.0	2	6.7	0	0.0	3	8.1	3	12.5
E - transient clinical improvement	5	17.2	4	18.2	8	26.7	5	50.0	8	21.6	3	12.5
F - no response to treatment	8	27.6	10	45.5	6	20.0	1	10.0	7	18.9	7	29.2
G - clinical deterioration	0	0.0	0	0.0	3	10.0	1	10.0	2	5.4	4	16.7
Good response (total A–C):	**14**	**48.3**	**8**	**36.4**	**11**	**36.7**	**3**	**30.0**	**17**	**45.9**	**7**	**29.2**
Inadequate response (total D–G):	**15**	**51.7**	**14**	**63.6**	**19**	**63.3**	**7**	**70.0**	**20**	**54.1**	**17**	**70.8**

Miedzybrodski et al. Clinical Aspects of Phage Therapy. 2012. Elsevier Advances in Virus Research, vol. 83, Part B, Bacteriophage, chapter 3: 74-119

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Today in the West

High renewed interest in phage therapy

but

phages should go through the same process as any medicine

i.e. clinical trials with GMP produced phages

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Today in the West

EudraCT 2004-001691-39, Biocontrol Ltd. (Ampliphi Bioscience corp. subsidiary)

A controlled clinical trial of a therapeutic bacteriophage preparation in chronic otitis due to antibiotic-resistant *P. aeruginosa*; a preliminary report of efficacy

Wright, A et al. Clin. Otolaryngol. 2009; Vol 34:349-357

Design

- Placebo-controlled, randomized, double-blind phase I/II
- Topical single dose of phage cocktail
- 6 phages anti *P. aeruginosa* @ 6.10^5 pfu/mL
- Follow up 7, 21, and 42 days post-treatment

Participants

- 24 patients with chronic otitis (2-58 years)

Results

- No adverse events related to phage treatment
- Clinical indicators (main outcome) improved in phage group
- *P. aeruginosa* counts (secondary outcome) decreased in phage group

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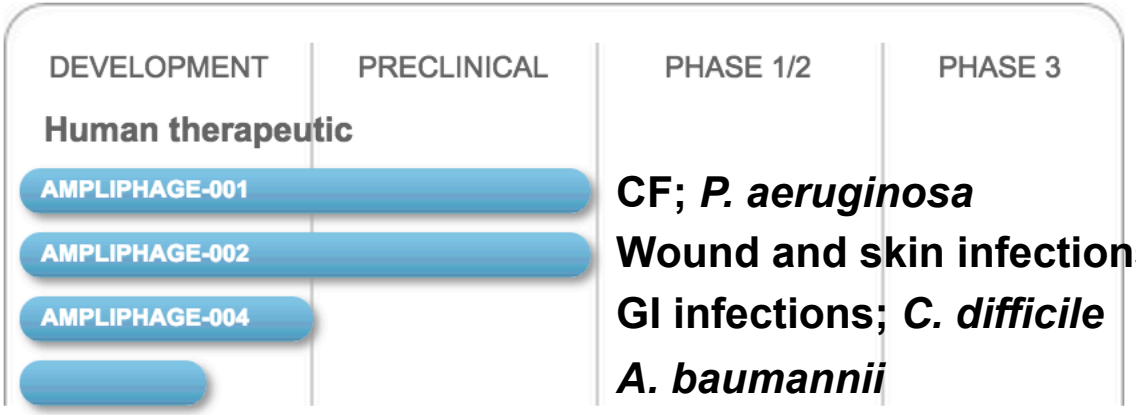
Today in the West

AMPLIPHI BIOSCIENCES CORPORATION

Innovative Solutions for Antibiotic Resistance

Infection control, amplified

AmpliPhi's product development pathway



The Company's leading bacteriophage therapeutic programs target areas of significant unmet clinical need, and its proprietary technology has additional applications for the treatment of a broad range of serious infections.

Today in the West

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"
Search for studies: Search
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Condition: Diarrhea
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Today in the West

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Food Safety Environmental Sanitation Veterinary Applications Human Therapeutics

Intralytix, Inc.
Bacteriophage Research & Development

Food Safety Products

ListShield™
Targets *Listeria monocytogenes* contamination in foods and food processing facilities.

EcoShield™
Targets *Escherichia coli* O157:H7 contamination in foods and food processing facilities.

SalmoFresh™
Targets contamination with selected, highly pathogenic *Salmonella*-serotypes in foods and food processing facilities.

Probiotic/Nutraceutical Products

ShigActive™
Targets *Shigella* species in the gastrointestinal tract. This product is in development.

Animal Health Products

INT-401™
Targets *Clostridium perfringens* in live poultry. This product has been licensed out.

Product Details:

ListShield™
EcoShield™
SalmoFresh™

For product inquires or to place an order send an email to sales@intralytix.com.

Today in the West

Bacteriophage therapy of venous leg ulcers in humans: results of a phase I safety trial

Rhoads et al. J. of. Wound Care; Vol 18. N°6, June 2009

Design

- 8 phages (*S. aureus, P. aeruginosa, E. coli*) @ 5.10^8 PFU/mL
- Topical once a week for 12 weeks

Participants

- 39 patients with chronic leg ulcers

Results

- No adverse events related to phage treatment

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Today in the West

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Today in the West

Antibacterial treatment against diarrhea in oral rehydration solution
Vandenheuvel et al. Annu. Rev. Virol. 2015, 2:11.1-11.20

Design
- Randomized, double-blind and placebo controlled Phase I/II trial
- T4-like phage cocktail
- Oral, twice daily over 4 days

Participants
- 120 children with acute *E.coli*-related diarrhea

Results
- No adverse events related to phage treatment
- No significant differences on quantitative diarrhea parameters

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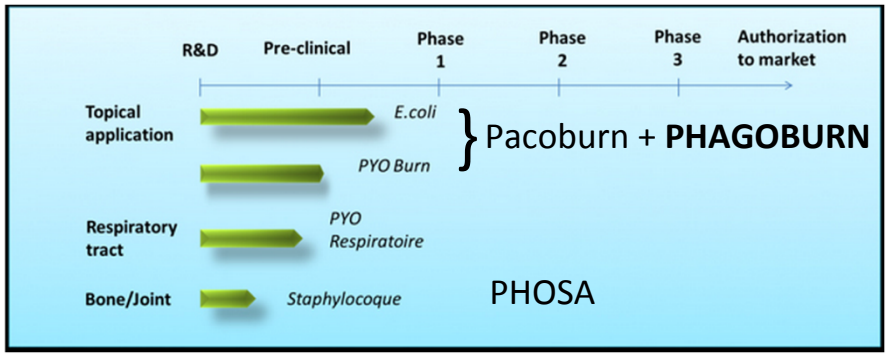
Today in the West

Development prospects

The following drug development pipeline illustrates Company's product development stage.



Pherecydes Pharma drug development pipeline

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PhagoBurn

Evaluation of phage therapy for the treatment of *E. coli* and *P. aeruginosa* wound infections in burned patients

Phase I/II randomized, **multicentric**, open label, standard of care-controlled
with GMP produced phages

Objective

- Assess tolerance and efficacy of 2 topical phage cocktails

Study Population

- 220 hospitalized adults with 3rd degree burn wounds infected with *E. coli* or *P. aeruginosa*

Primary outcome

- Time from D0 to 2 quadrants reduction in pathogen load

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PhagoBurn

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Service de Santé des Armées

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CHU de Liège

Centre Hospitalier Régional METZ-THIONVILLE

GHdC asbl

Assistance Publique Hôpitaux de Marseille

C·H·U Hôpitaux de Bordeaux

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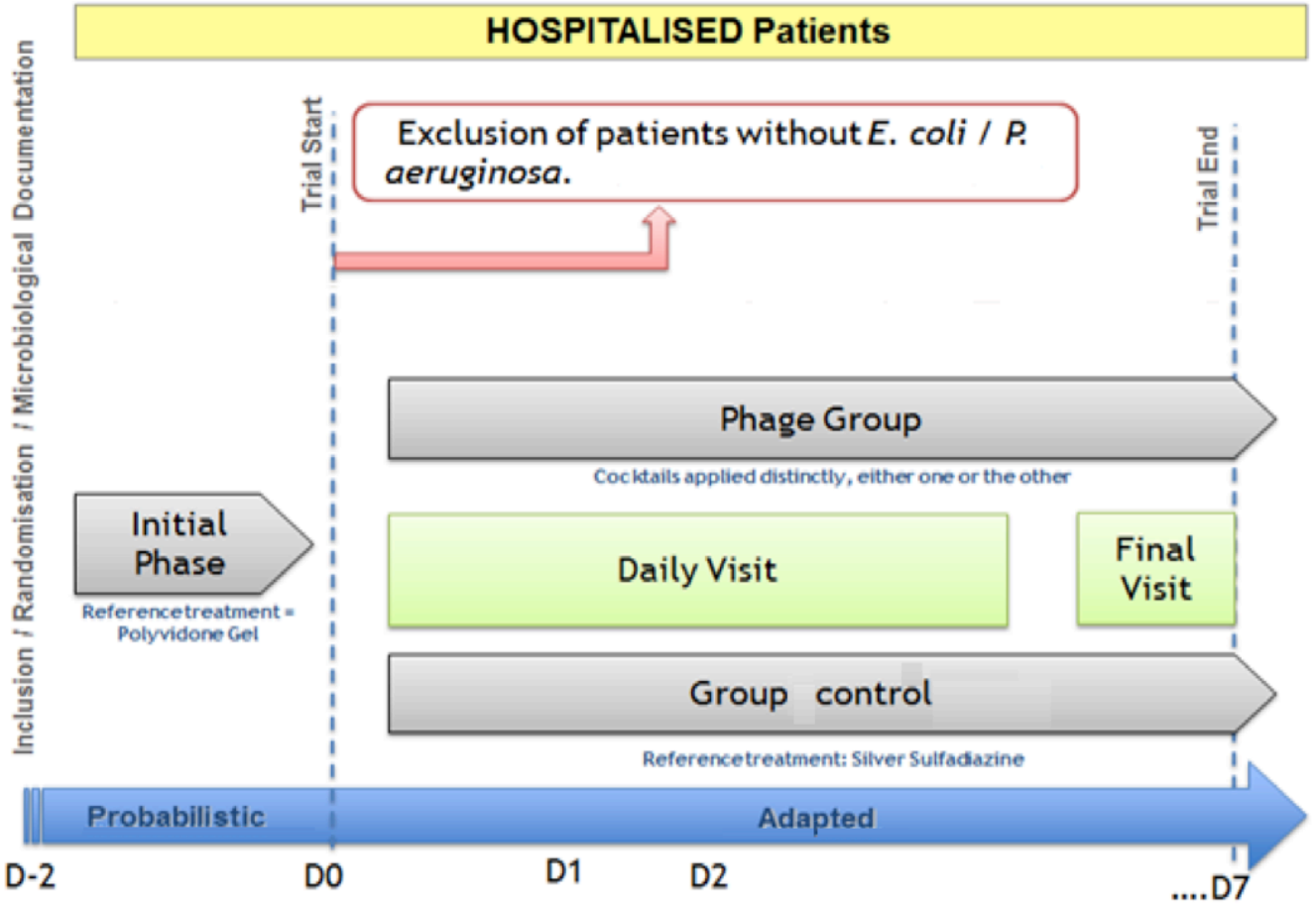
PhagoBurn

4 arms

- *P. aeruginosa* treated with phage cocktail (55 patients) or SOC (55 patients)
- *E. coli* treated with phage cocktail (55 patients) or SOC (55 patients)



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PhagoBurn

- ✓ Phage cocktails produced in GMP conditions
  - ✓ 12 phages for *E. coli*
  - ✓ 13 phages for *P. aeruginosa*

- ✓ Approval of trial by the 3 National Authorities and Ethical Committees

- ✓ 07/21/2015: First inclusion (France)

- ✓ Results in one year

www.phagoburn.eu

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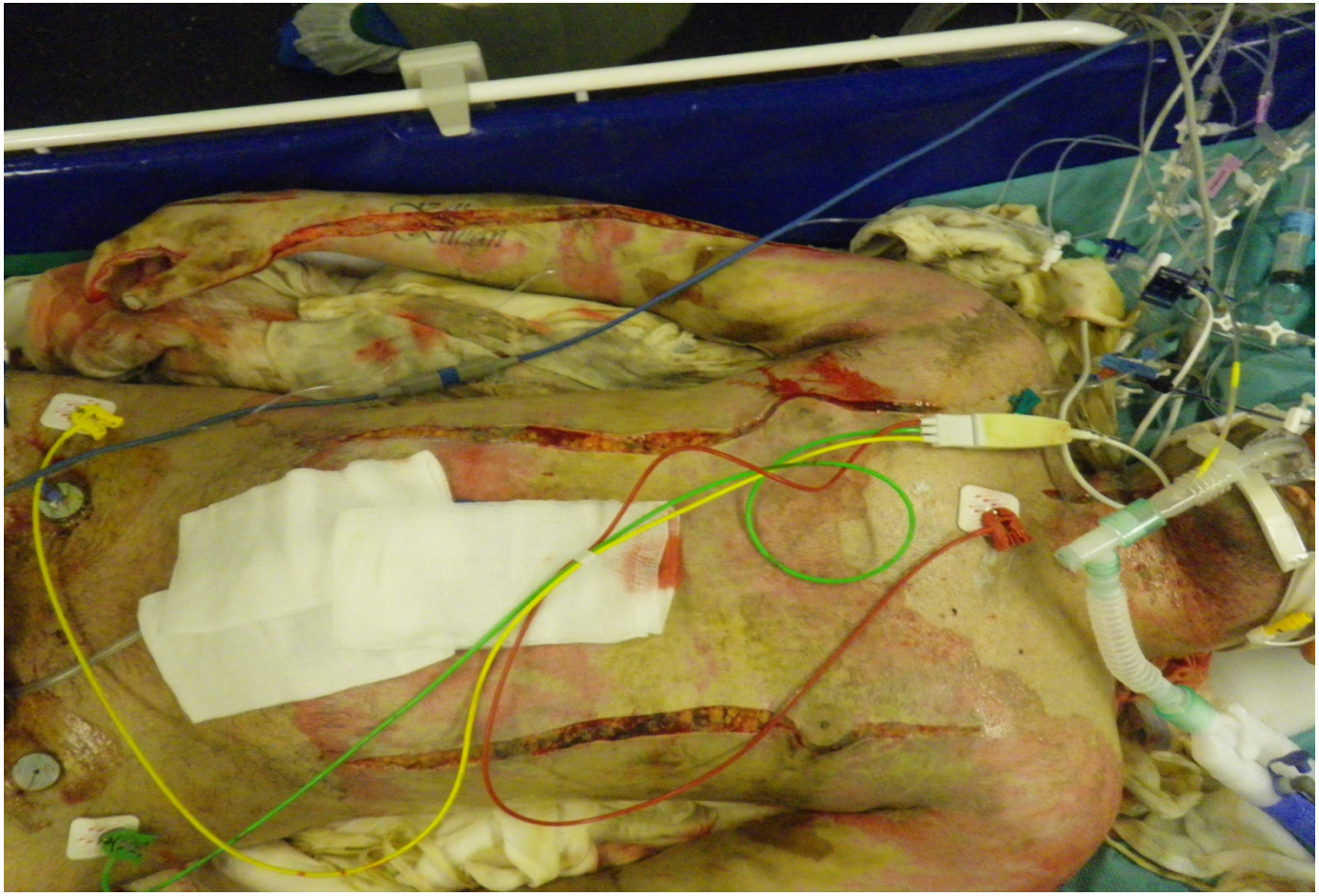
P. aeruginosa infections in BICUs

Example of MDR development : Pan-resistance

> 90% TBSA



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P. aeruginosa infections in BICUs

Example of MDR development : Pan-resistance

Antibiograms	Feb. 04 2013	Apr. 02 2013	Apr. 25 2013	Apr. 29 2013	May 01 2013
Pipéracillin-tazobactam	S	R	R	R	R
Ceftazidime	S	R	R	R	R
Cefepime	S	R	R	R	R
Imipenem	R	R	R	R	R
Meropenem	I	R	R		
Aztreonam	I	R	R		
Amikacin	S	S	R		
Gentamicin	S	R	R		
Tobramycin	S	S	R	R	R
Colistin	S	S	S	S	R
Co-trimoxazole	R	R	R	R	R
Ciprofloxacine	S	S	R	R	R
Levofloxacin	S	R	R	R	R

May 1st 2013
214 days after injury
DEATH

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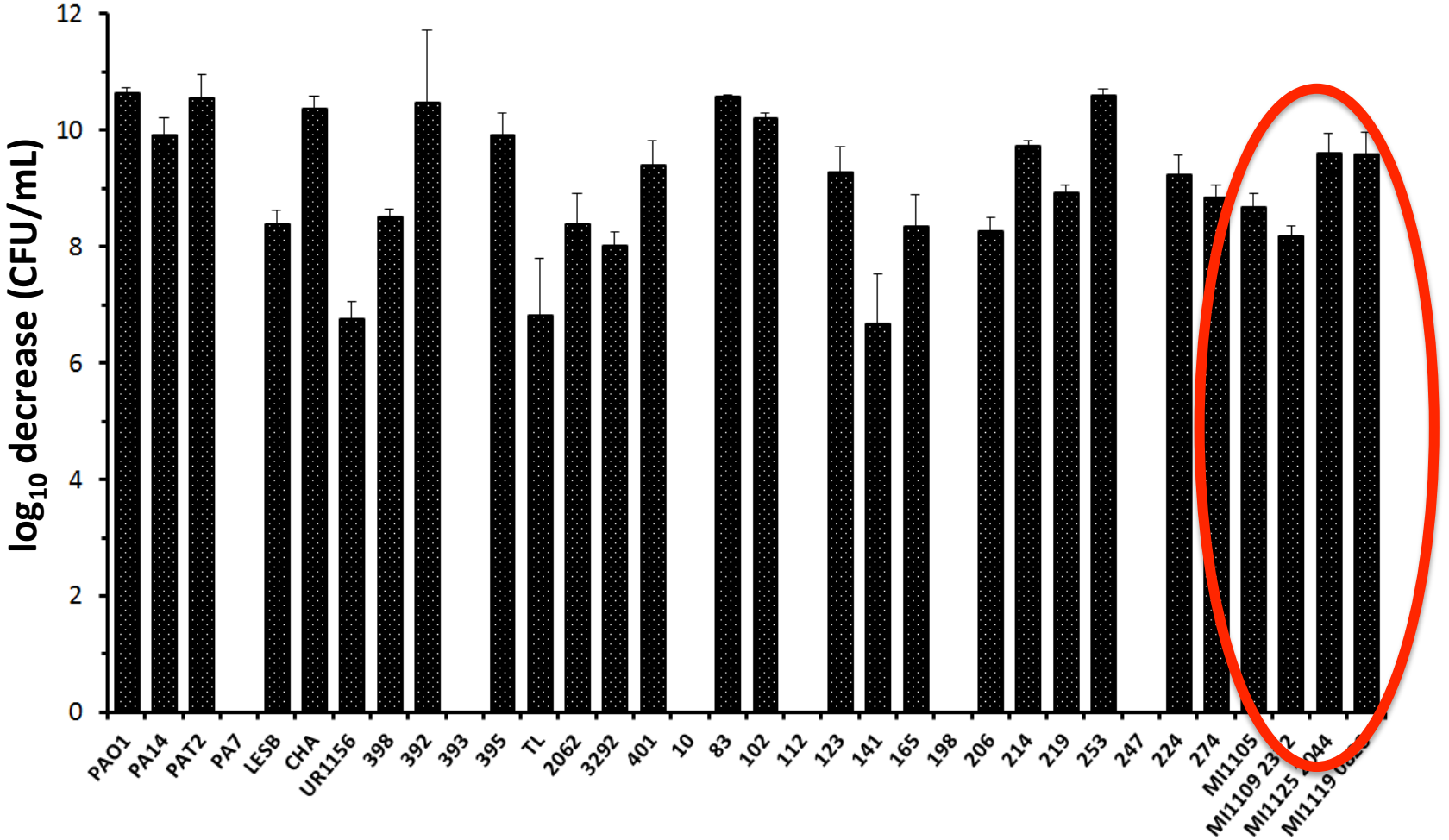
PhagoBurn



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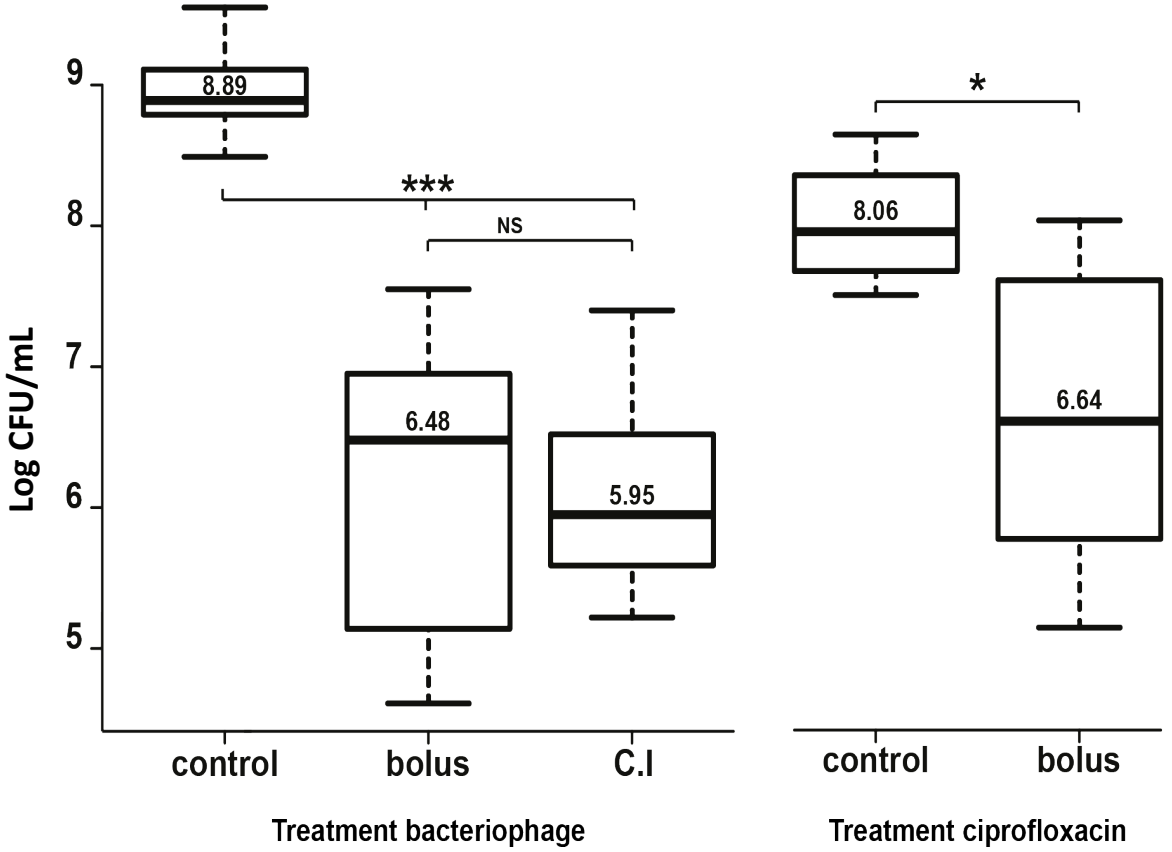
Hope you didn't miss!

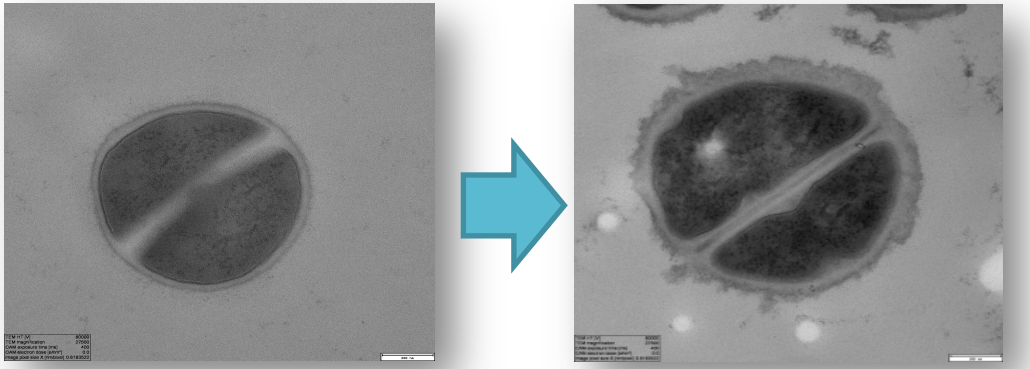
Frank Oechslin (Poster B-060), today 12 to 2pm

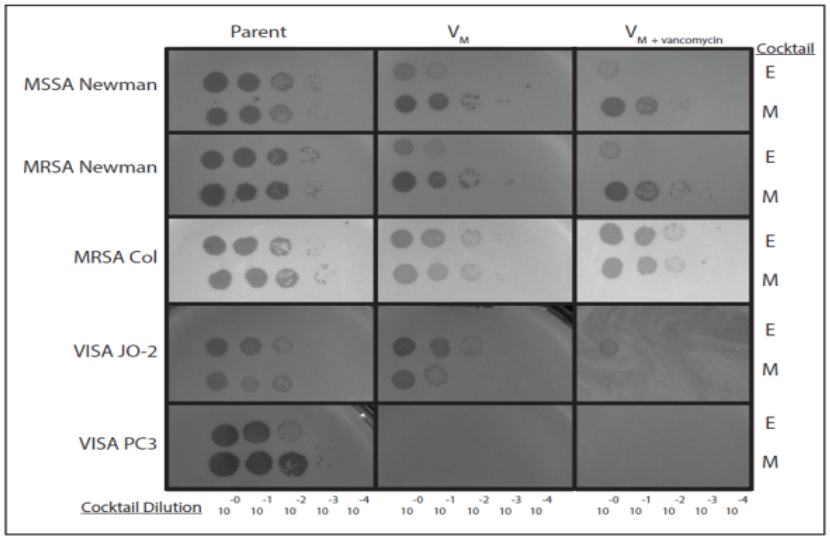
Phage Therapy vs Antibiotherapy in Experimental Endocarditis



Don’t miss!

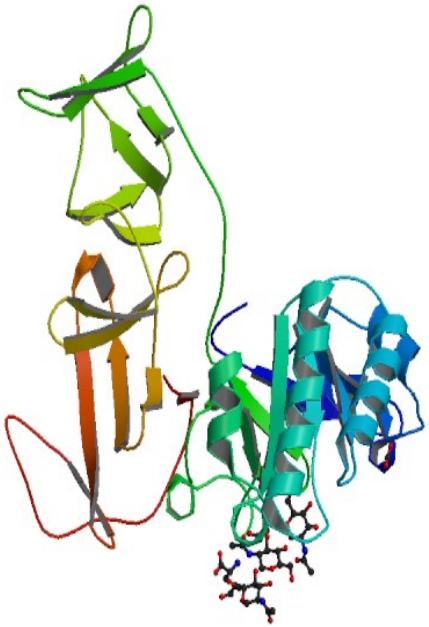
Shawna McCallin (Poster C-1069), Sunday 11am to 2pm
Phage-Antibiotic Combination: The Case of Vancomycin



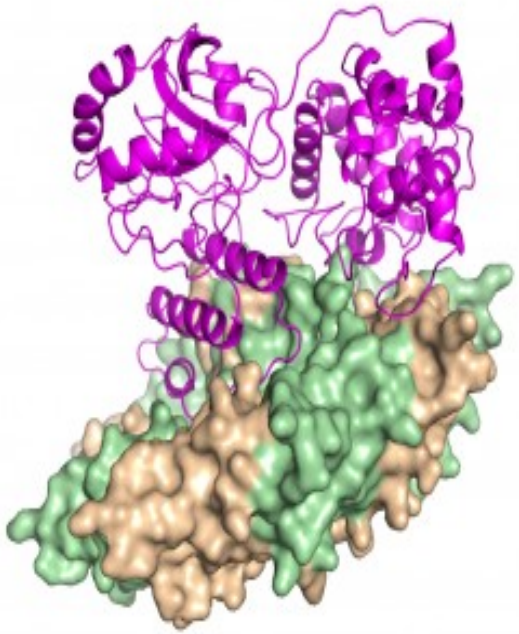


Phage-Based Therapies

Phage Lysins Therapy



Cpl-1; J. Biol. Chem. 282 (34): 24990–9



PlyC; EARTHSKY//SCIENCE WIRE. Jul. 24, 2012

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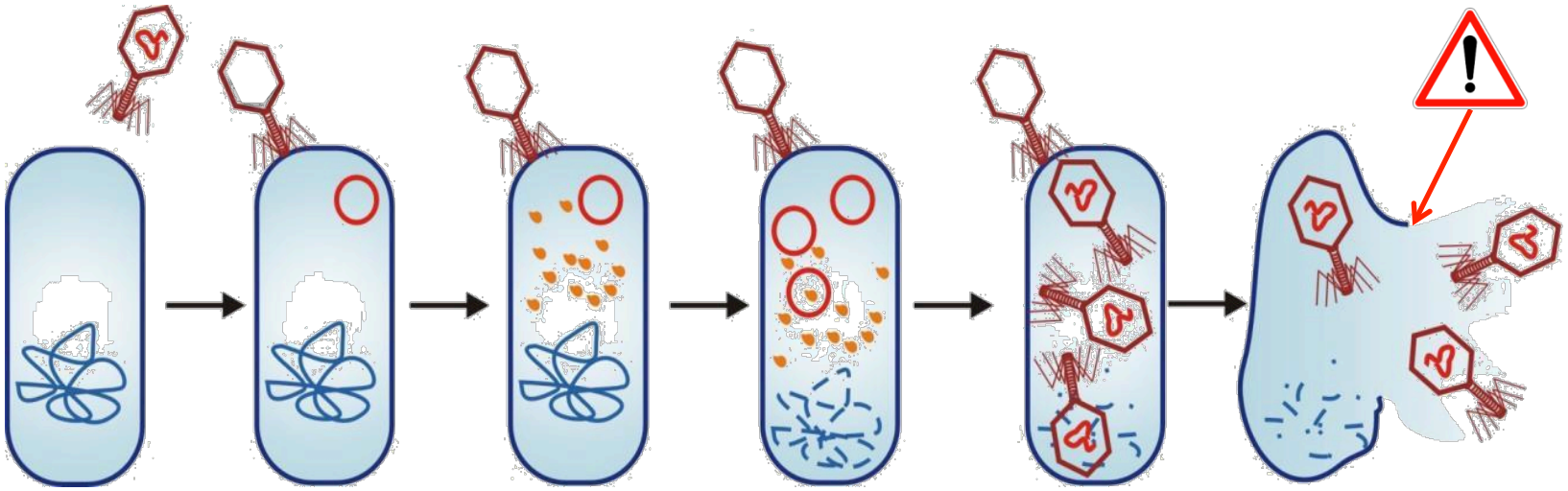
What is behind phage therapy?

The life cycle of lytic bacteriophage



courtesy of De Vos D. (PHAGOBURN kick-off meeting)

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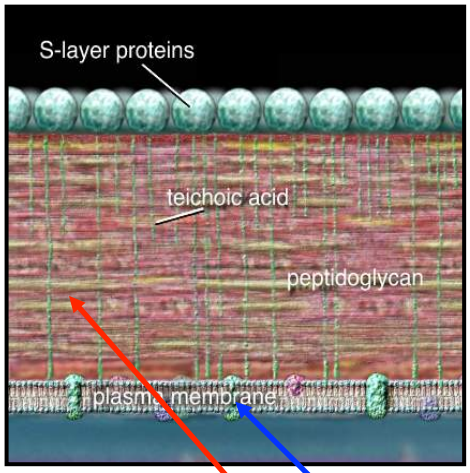
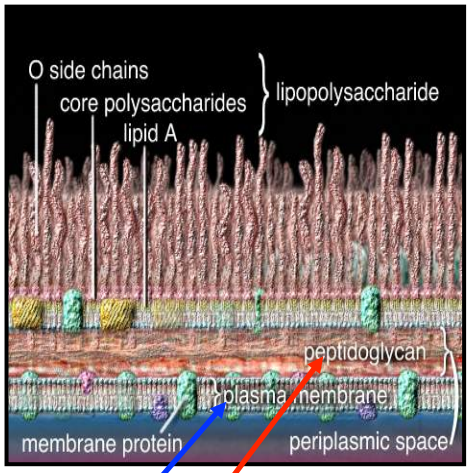
Phage Lysin Therapy

The Holin-Lysin enzymatic system

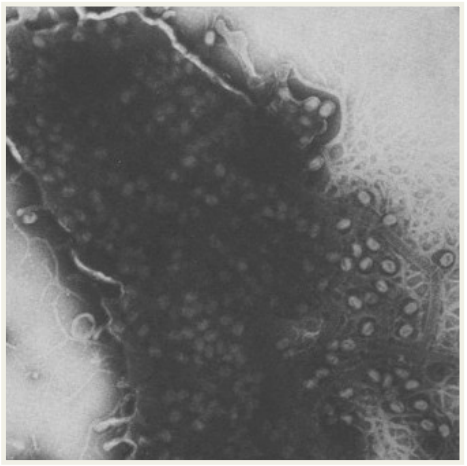
Surrounding media



Gram+



Gram-



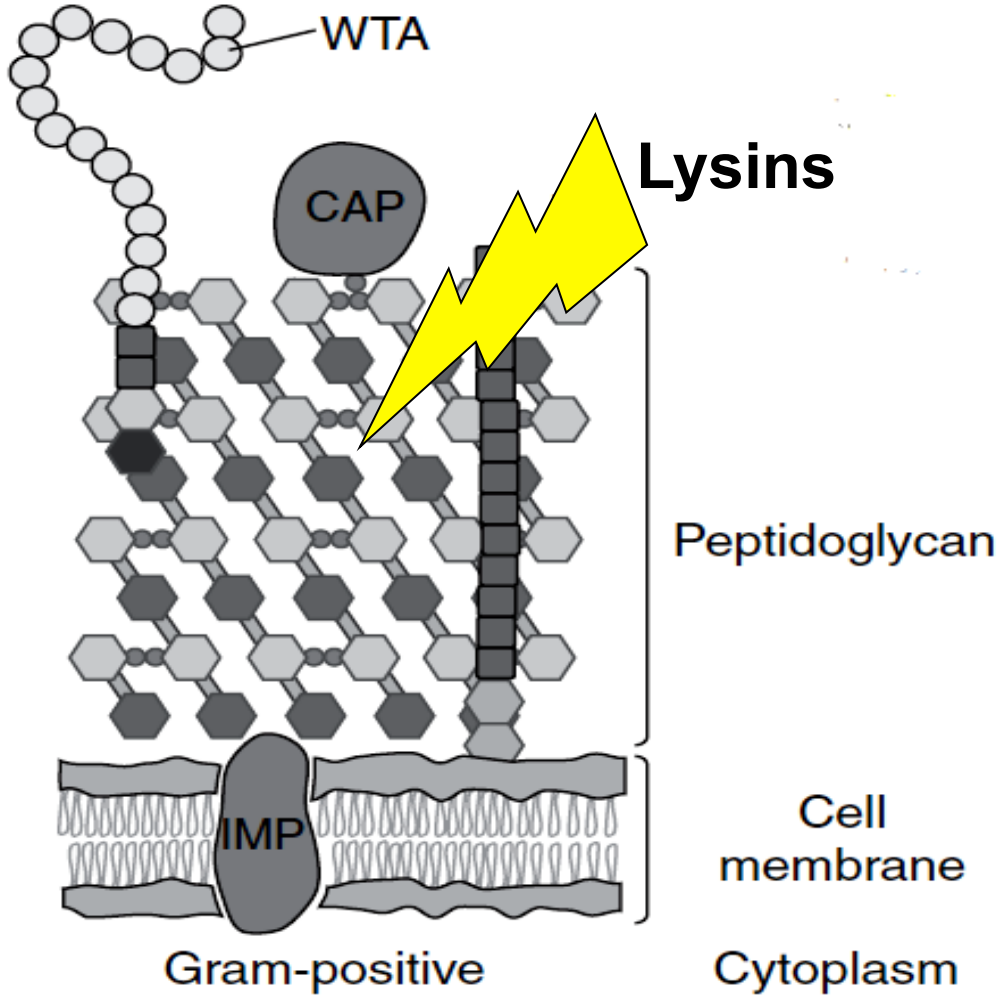
Holin

Lysin

Cytoplasm

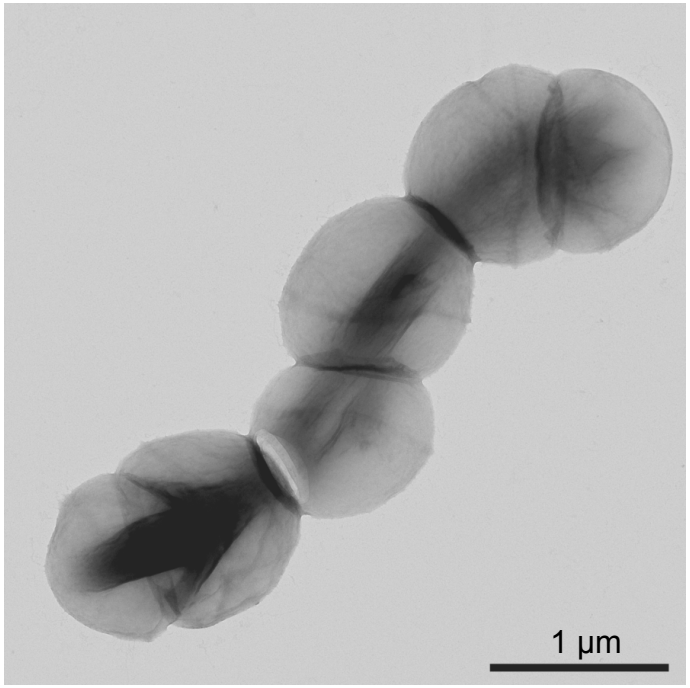
Phage Lysin Therapy

Purified Lysins on Gram+ = lysis from the outside

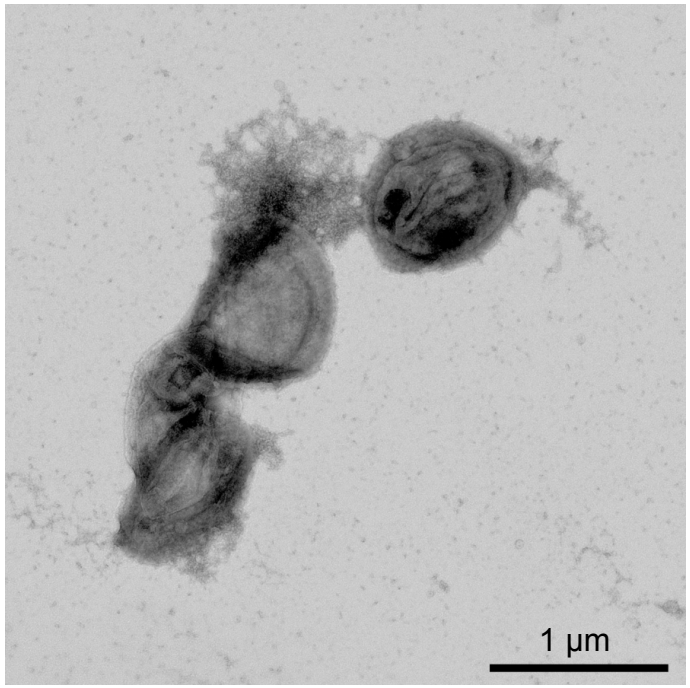


Phage Lysin Therapy

PlySK1249 *in vitro* activity



No PlySK1249



+ PlySK1249

Oechslin et al. AAC. 2013 Dec;57(12):676-83

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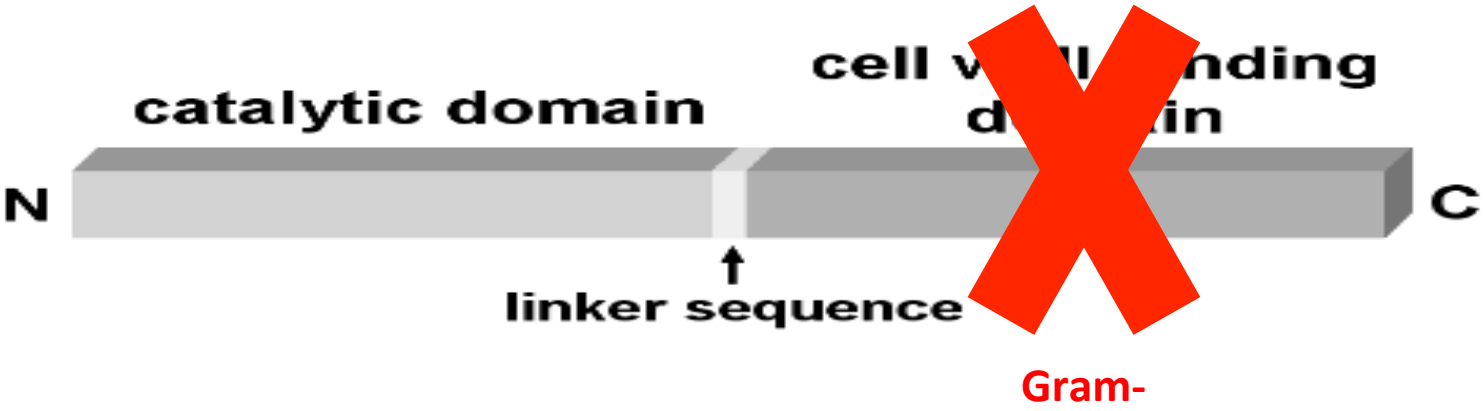

Exceptions exist

PlyC multimeric (1 plyCA + 8 plyBC)
Nelson et al. PNAS. 2006 Jul 11;103(28):10765-70

PlySK1249 : 2 CD + 1 central CBD
Oechslin et al. AAC. 2013 Dec;57(12):676-83

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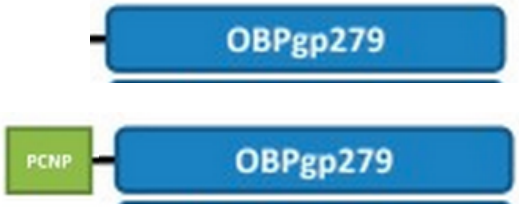
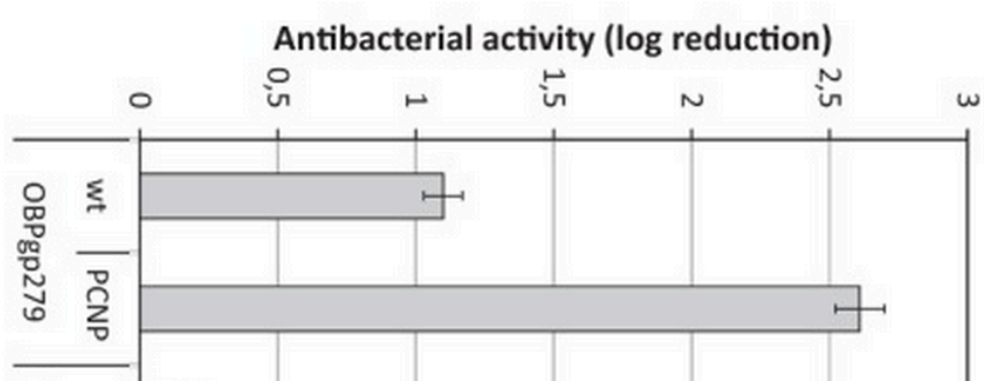
Lysins active against Gram-

Artilysins





Briers Y, et al. Mbio. 2014 Jul 1;5(4):e01379-24.

Natural lysins (PlyF307)

Novel phage lysin capable of killing the multidrug-resistant Gram- *Acinetobacter baumannii* in a mouse bacteremia model

Lood R, et al. Antimicrob. Agents. Chemother. 2015 Apr;59(4):1983-91

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Phage Lysin Therapy

- High specificity
- Act in seconds or minutes
- Not neutralized by antibodies
- Can be engineered (chimera, dimers)
- Synergy with antibiotics
  - Cpl-1+daptomycin. Vouillamoz et al. IJAA. 2013 Nov;42(5):416-21

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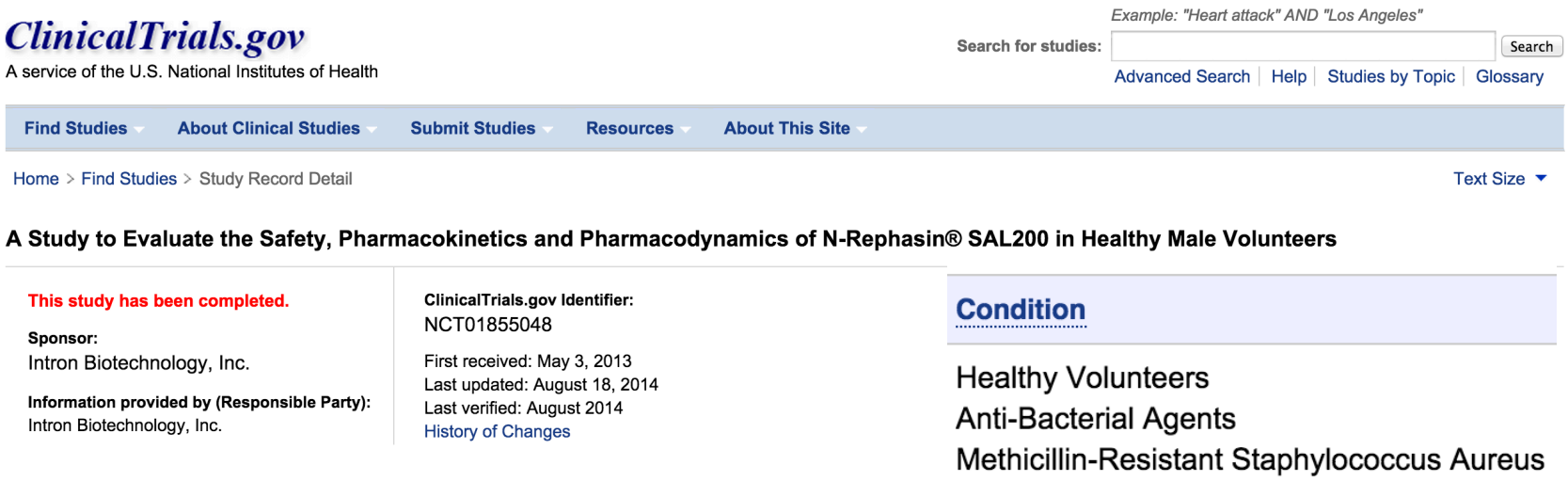

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"
Search for studies: Search
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Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

Home > Find Studies > Study Record Detail

Text Size

A Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of N-Rephasin® SAL200 in Healthy Male Volunteers

This study has been completed.

Sponsor:
Intron Biotechnology, Inc.

Information provided by (Responsible Party):
Intron Biotechnology, Inc.

ClinicalTrials.gov Identifier:
NCT01855048

First received: May 3, 2013
Last updated: August 18, 2014
Last verified: August 2014
History of Changes

Condition

Healthy Volunteers
Anti-Bacterial Agents
Methicillin-Resistant Staphylococcus Aureus

Design

- Randomized, double-blind Phase I
- Continuous intravenous infusion over 60 minutes

Participants

- 36 healthy male volunteers (20-45 years old)

Results

- No adverse events
- Ready for Phase II

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Phage Lysin Therapy

Poster F-290b
today, 12 to 2pm
Schuch R.

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Phage Lysin Therapy

A Placebo-Controlled, Dose-Escalating Study to Examine the Safety and Tolerability of Single Intravenous Doses of CF-301 in Healthy Subjects

This study is currently recruiting participants. (see Contacts and Locations)

Verified April 2015 by ContraFect

Sponsor:
ContraFect

Information provided by (Responsible Party):
ContraFect

ClinicalTrials.gov Identifier:
NCT02439359

First received: April 27, 2015
Last updated: May 6, 2015
Last verified: April 2015
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

A Phase 1, Placebo-Controlled, Dose-Escalating Study to Examine the Safety and Tolerability of Single Intravenous Doses of **CF-301** in Healthy Subjects.

Condition	Intervention	Phase
Staphylococcus Aureus Bloodstream Infections (BSI; Bacteremia)	Drug: **CF-301** Drug: Placebo	Phase 1

Granted FDA Fast Track

Design

- Randomized, double-blind, dose-escalating Phase I
- Intravenous injection of single doses

Participants

- 24 healthy volunteers

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Conclusions

Take home messages

Phages and Phage Lysins are promising new antibacterial agents

Things are currently moving fast in both fields in the West

- significant clinical trials are ongoing

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Acknowledgments 1

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PhagoBurn

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UNION EUROPEENNE

SEVENTH FRAMEWORK PROGRAMME

Acknowledgments 3

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CHUV

SMIA

FNSNF
FONDS NATIONAL SUISSE
DE LA RECHERCHE SCIENTIFIQUE

LOTERIE ROMANDE

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Thank you for your attention

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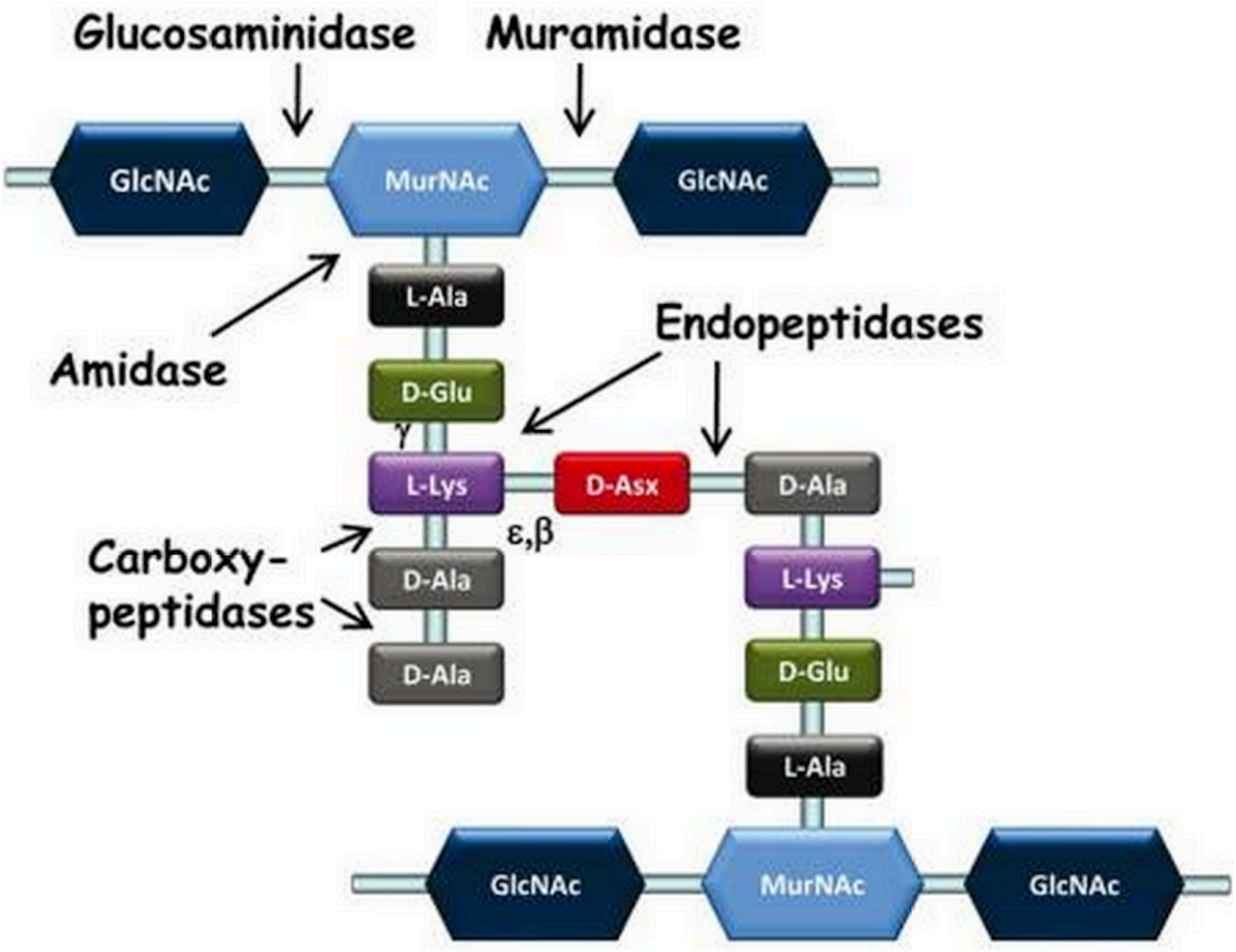
Phage Lysin Therapy



adapted from Chapot-Chartier MP. Frontiers in Microbiology May 2014(5);Article 236:1-10.

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Phage Lysin Therapy

MICREOS

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Micreos Human Health

Micreos Human Health is committed to the development of targeted antibacterial products against harmful bacteria, both preventively and curatively.

In 2013 we introduced a first series of products for human health under the Gladskin brand for people with skin conditions with an infectious component, such as acne, eczema, psoriasis and rosacea. In October 2014 we introduced Staphefekt XDR.300, against *S. aureus* including MRSA.

Our pipeline also includes products against *E. coli* in childhood diarrhoea in developing and threshold countries, and *C. difficile,* a very resistant bacterial species which can cause fatal hospital diarrhoea.

Latest fact sheets on:

Acne	Micreos Staphefekt SA.100 (Gladskin)	Download
Colonization Infection Continuum	Micreos Staphefekt SA.100	Download
Folliculitis/Furunculosis	Micreos Staphefekt SA.100 (Gladskin)	Download
Rosacea	Micreos Staphefekt SA.100 (Gladskin)	Download
Staphylococcus aureus	Micreos Staphefekt SA.100	Download

Micreos: Solutions for Life

NEWS

Interview on Radio 1 with microbiologist Bjorn Herpers
Interview (Dutch) Radio 1 with microbiologist Bjorn Herpers about antimicrobial resistance and Mi ...

Future innovations: What are the alternatives to antibiotics?
Micreos featured in Pharmafocus. Click here to view the Article (PDF)